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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

PURGED

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1888
Telephone: 612-334-4100

December 31, 1996

cc: HFI-35/FOI S
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-20

Anthony Palermo
Chairman of the Board and CEO
Modern Products
3015 West Vera Avenue
Milwaukee, Wisconsin 53209

Dear Mr. Palermo:

During our inspection on December 5, 6 and 10, 1996, of your drug manufacturing facility located in Milwaukee, WI, FDA Investigator John Hermann observed serious deviations from current Good Manufacturing Practice Regulations, Title 21, Code of Federal Regulations, Parts 210 and 211 (GMP). Manufacture and packaging of Swiss Kriss Laxative products in a facility which is operated without conformance with GMP causes these products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Deviations from GMP which were observed and documented by Mr. Hermann include but are not limited to:

1. Failure to make the tamper resistant packaging of Swiss Kriss Flakes "distinctive by design."

2. Failure to perform finished product microbiological testing on Swiss Kriss Flakes since February 1995.

3. Failure to establish written batch formulations to assure products have the strength, quality and purity which they purport to possess.

4. Failure to establish a system to assign unique lot numbers for each production batch.

5. Failure to establish and maintain a complaint file.

6. Failure to establish and document a stability testing program to support the expiration dating of drug products.

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead.

Sincerely yours,

John Feldman
Director
Minneapolis District

LRM/ccl

xc: Gayelord Palermo
President
Modern Products
3015 West Vera Avenue
Milwaukee, WI 53209